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Bailout revascularization of chronic femoral artery occlusions with the new outback catheter following failed conventional endovascular intervention

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Abstract: PURPOSE: To report the application of a true lumen re-entry device in the bailout treatment of chronic total occlusions (CTO) of the superficial femoral artery (SFA) after failed angioplasty. **METHODS:** Nineteen patients (12 men; mean age 81 years, range 61-97) with 20 SFA CTOs and Rutherford category 2 to 5 ischemia were prospectively evaluated. All CTOs had unsuccessful recanalization using conventional techniques and were subsequently treated with the Outback LTD catheter. Follow-up at 3, 6, and 12 months included ankle/toe pressure measurement and pulse volume recordings. Endpoints were revascularization rate, target lesion revascularization, and limb salvage. **RESULTS:** Revascularization was achieved in 95% of the cases. There were 2 (10%) periprocedural complications unrelated to the re-entry device, which were resolved by endovascular or surgical treatment. The target lesion revascularization rate was 10%, with the 2 events occurring at 3 and 6 months, respectively, in patients with Rutherford category 4-5 ischemia. There was one below-the-knee amputation in the patient with failed revascularization. **CONCLUSION:** The acute failure of endovascular treatment of SFA CTOs is most often due to an inability to re-enter the true lumen after the occlusion is crossed in a subintimal plane. Bailout revascularization with the Outback LTD catheter is highly successful and shows a low device-related complication rate. This needle- and fluoroscopic-based re-entry device increases the endovascular success rate and is therefore expanding the minimally invasive treatment options for surgically unfit patients.

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◆ CLINICAL INVESTIGATION ◆

Bailout Revascularization of Chronic Femoral Artery Occlusions With the New Outback Catheter Following Failed Conventional Endovascular Intervention

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Purpose: To report the application of a true lumen re-entry device in the bailout treatment of chronic total occlusions (CTO) of the superficial femoral artery (SFA) after failed angioplasty.

Methods: Nineteen patients (12 men; mean age 81 years, range 61–97) with 20 SFA CTOs and Rutherford category 2 to 5 ischemia were prospectively evaluated. All CTOs had unsuccessful recanalization using conventional techniques and were subsequently treated with the Outback LTD catheter. Follow-up at 3, 6, and 12 months included ankle/toe pressure measurement and pulse volume recordings. Endpoints were revascularization rate, target lesion revascularization, and limb salvage.

Results: Revascularization was achieved in 95% of the cases. There were 2 (10%) periprocedural complications unrelated to the re-entry device, which were resolved by endovascular or surgical treatment. The target lesion revascularization rate was 10%, with the 2 events occurring at 3 and 6 months, respectively, in patients with Rutherford category 4–5 ischemia. There was one below-the-knee amputation in the patient with failed revascularization.

Conclusion: The acute failure of endovascular treatment of SFA CTOs is most often due to an inability to re-enter the true lumen after the occlusion is crossed in a subintimal plane. Bailout revascularization with the Outback LTD catheter is highly successful and shows a low device-related complication rate. This needle- and fluoroscopic-based re-entry device increases the endovascular success rate and is therefore expanding the minimally invasive treatment options for surgically unfit patients.

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Key words: chronic total occlusion, superficial femoral artery, subintimal recanalization, re-entry device, radiographically-guided navigation

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Endovascular management of chronic total occlusion (CTO) is not feasible in up to 25% of the cases depending on the length and calcification of the occluded segment.¹ In calcified CTOs, recanalization is frequently performed over the subintimal route.² Re-entry of the guidewire into the true lumen is the keystone of success and a main cause of

failure in these subintimal procedures. However, in some cases, true lumen re-entry is not achieved until subintimal passage to a site far from the level of vessel lumen patency, leading to possible potential damage of side branches or vessel segments suitable for distal anastomosis of a potential bypass. Therefore, two different guidance techniques

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TABLE 1Clinical Characteristics of 19 Patients With 20
Chronic Total SFA Occlusions

Age, y	81 (61–97)
Men	12 (60%)
Body mass index, kg/m ²	24.0 ± 4.4
Hypertension	17 (89%)
Diabetes mellitus	3 (6%)
Dyslipidemia	12 (67%)
Smoking	9 (50%)
Coronary artery disease	8 (44%)
Cerebrovascular disease	1 (6%)
Rutherford category	
2–3	4 (20%)
4	2 (10%)
5	14 (70%)
Occlusion length, cm	17 (5–40)
TASC lesion class	
C	16 (80%)
D	4 (20%)
De novo lesion	17 (85%)
Recurrent occlusion after PTA	3 (15%)

Continuous data are presented as means ± standard deviation or (range); categorical data are given as counts (percentages).

TASC: TransAtlantic Inter-Society Consensus, PTA: percutaneous transluminal angioplasty.

for needle catheter systems have been developed to facilitate true lumen re-entry: intravascular ultrasound (IVUS) and fluoroscopy.^{1,3,4} IVUS navigation, which is available with the Pioneer catheter, is more expensive and demands an ultrasound console as well as additional skills, whereas the Outback catheter allows direct fluoroscopic navigation. Early studies using the Outback Catheter system reported an inadequate technical success rate, especially in calcified occlusions,⁴ so the design was re-engineered to incorporate a stiffer needle and a lateral exit port.

We report our first consecutive series of endovascular treatments using the new Outback LTD re-entry catheter system as a bailout procedure in patients with CTOs in the superficial femoral artery (SFA).

METHODS

Patient Population

A study was conducted under Institutional Review Board approval to retrospectively review all patients who had bailout endovas-

cular treatment with the Outback LTD catheter (Cordis, a Johnson & Johnson company, Miami Lakes, FL, USA) from December 2006 to December 2007. All patients had given informed consent before the procedure and had SFA CTOs in which standard catheter and guidewire techniques had failed. Interrogation of the department's prospectively maintained database identified 19 patients (12 men; mean age 81 years, range 61–97) with 20 SFA CTOs (Table 1) treated with the Outback catheter system in this time period. Data were gathered on demographic and baseline characteristics, clinical presentation, imaging studies, treatment modality, and prospective follow-up at 3, 6, and 12 months.

Vascular Assessment and Follow-up

Assessment of peripheral circulation was performed at baseline and at every follow-up visit using noninvasive vascular tests that included measurement of the systolic blood pressure of both the anterior and posterior tibial arteries and calculation of the ankle-brachial index (ABI). Photoplethysmography to measure great toe pressures was used in arteries that were considered incompressible (ABI >1.3) or in which oscillometric readings showed poor pulsatility despite absolute ankle pressures >50 mmHg. Imaging studies with duplex ultrasound or angiography were completed in all patients at baseline and during follow-up in cases in which recurrent stenosis or occlusion or additional arterial lesions were suspected clinically or hemodynamically.

Subintimal Re-Entry Procedure

Arterial access was either retrograde cross-over or antegrade femoral. All patients were systemically heparinized before the CTO was manipulated. CTOs (Fig. 1A) were crossed with either a hydrophilic 0.035-inch guidewire (Radifocus; Terumo GmbH, Wettingen, Switzerland) or a 0.018-inch Control wire (Boston Scientific, Natick, MA, USA). Additional support catheters were used as needed. Occasionally, balloon angioplasty in a segment of the occlusion was required to facilitate navigation through the remaining occlusion (Fig. 1B). No standard technique was used

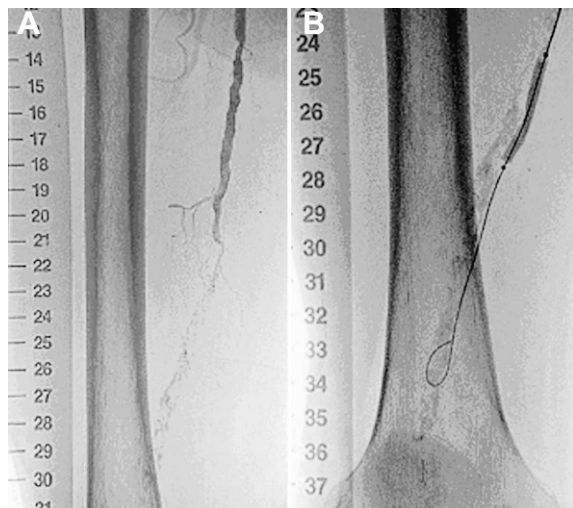


Figure 1 ♦ (A) Angiogram showing a 15-cm-long occlusion of the SFA. (B) Predilation (3- \times 40-mm balloon) to facilitate subintimal passage of the Outback LTD catheter to the re-entry target at the 36-cm level on the popliteal artery.

to intentionally place the wire subintimally; however, subintimal passage was assumed in all of the CTO crossings, which required the use of true lumen re-entry maneuvers and devices. Attempts to gain access to the true lumen with catheter wire manipulations were routinely made using additional catheters and wires with different tip configurations. If these attempts to access the true lumen failed, the Outback LTD catheter true lumen re-entry device was used.

The Outback LTD re-entry catheter is a single-lumen, over-the-wire, 6-F sheath-compatible catheter with a curved nitinol cannula within the outer shaft running the full length of the catheter to serve as the guidewire lumen. In contrast to the first-generation device, the new catheter has an end port and a lateral exit port. The nosecone at the catheter tip possesses an L-shaped radiopaque marker indicating needle direction. When the image intensifier is orthogonally moved, a "T" shape appears to check whether the catheter is overlying the artery to confirm alignment of the catheter to the artery. Guiding the catheter proximally or distally in the coaxial direction over a 0.014-inch guidewire allows positioning at the desired re-entry level. After assuring that the catheter is "in line" with the vessel (T-marker

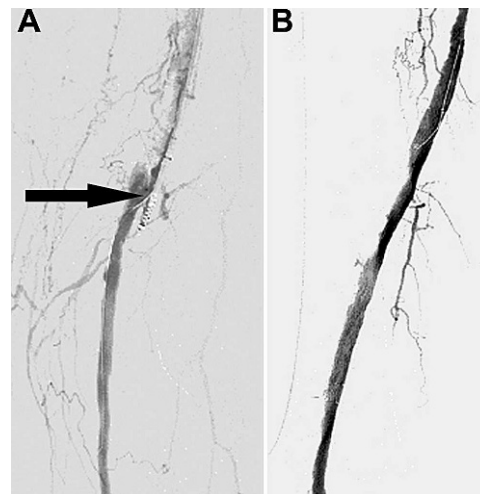


Figure 2 ♦ (A) Needle deployment (arrow) and a 0.014-inch guidewire advanced through the needle into the proximal patent popliteal artery. (B) Final angiogram after stenting of the superficial femoral artery.

"on top" of the artery) and that the cannula is pointing toward the target lumen (shown by L-marker when the image intensifier is turned by 90°), the 0.014-inch guidewire is retracted. The curved cannula tip is deployed from the catheter's lateral exit port through the intima into the true lumen. Upon proper placement of the needle tip, the parked guidewire is advanced through the curved cannula tip into the true lumen. Afterward, the cannula tip and subsequently the Outback LTD catheter can be removed, leaving the guidewire in place (Fig. 2A). After successful controlled re-entry is achieved, angioplasty and stenting can be performed over the 0.014-inch guidewire or over an exchanged 0.018-inch wire. In our series, all femoral artery occlusions were dilated and provisionally stented with self-expanding nitinol stents (Fig. 2B). All patients were treated with dual antiplatelet therapy (100-mg/d aspirin and 75-mg/d clopidogrel) for a minimum of 4 weeks.

Endpoint and Outcome Analysis

The primary endpoint was revascularization success; secondary endpoints were the analysis of repeated lesion revascularization (TLR), minor and major amputation, and minor and major complications. To document immediate hemodynamic success, clinical

evaluation and ABI or toe pressure measurements were performed 12 to 36 hours after endovascular treatment. Primary technical success was determined as true lumen access, whereas revascularization success encompassed an open femoropopliteal axis on angiography, with hemodynamic improvement of at least 0.1 for the ABI or 10 mmHg in the toe pressure.

Peri- and postinterventional complications were classified according to the reporting standards⁵ of the Society of Interventional Radiology and were documented up to 30 days. Minor complications were classified as (A) those requiring no therapy and having no consequence or (B) those having nominal therapy and no consequence (including overnight admission for observation only). Major complications were divided into 4 classes: (C) requiring therapy and/or short (<48 hours) hospitalization; (D) requiring major therapy, unplanned increase in the level of care, or prolonged (>48 hours) hospitalization; (E) resulting in permanent adverse sequelae; or (F) resulting in death.

Statistical Analysis

For continuous variables, values are given as either the mean with range or standard deviation or as the median with interquartile range (IQR) as indicated. For discrete variables, data are presented as the counts (percentages). The Wilcoxon signed rank test was used for comparison of pre- and post-interventional ABIs and toe pressures.

RESULTS

A femoral crossover technique was used in 60% of the revascularization procedures, which were successful in 19 (95%) of 20 lesions on an intention-to-treat basis. In the failed case, the device could not be removed and leave the guidewire in place due to kinking in a crossover access. Subsequently, the true lumen access was lost due to retraction of the kinked guidewire. This patient was considered unfit for bypass surgery and underwent below-the-knee amputation; he died 1 month later due to cardiac insufficiency.

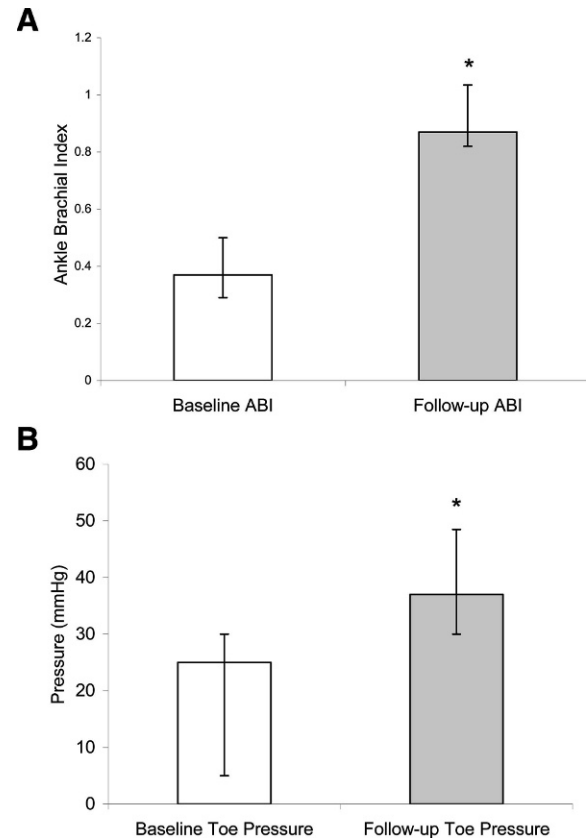


Figure 3 ♦ Median and interquartile ranges of ankle-brachial indexes (A) and toe pressures (B) at baseline and after subintimal bailout revascularization with the Outback LTD catheter. Toe pressure was taken in presence of incompressible tibial arteries. * $p < 0.0001$.

One patient needed additional abciximab therapy due to intravascular thrombosis during the procedure, which was concluded successfully. The median baseline ABI was 0.37 (IQR 0.25–0.5), and the median toe pressure was 25 mmHg (IQR 5–30); both increased significantly ($p < 0.0001$) after revascularization to 0.87 (IQR 0.82–1.03) and 37 mmHg (IQR 30–50), respectively (Fig. 3).

Periprocedural Complications

There were 2 (10%) major complications not related to the re-entry device requiring additional interventions. In one case involving a crossover access for the treatment of a left femoral CTO, plaque dislocation occurred at the right femoral sheath insertion site, with

TABLE 2
Follow-up Examinations, Recurrences, and Target Lesion Revascularizations

	Baseline	1 Month	3 Months	6 Months	12 Months
Number of patients	19	15	14	14	6
Number of lesions	20	16	15	14	6
Rutherford 2-3					
Examinations	4	9	12	11	5
Recurrence		0	0	1†	1§
Reintervention		0	0	0	0
Rutherford 4-5					
Examinations	16	7	3	3	1
Recurrence		0	1*	1‡	0
Reintervention		0	1*	1‡	0
Amputation		1	0	0	0

* Restenosis >50% in a 74-year-old man with a 5-cm occlusion at primary intervention.

† Restenosis 50% in a 62-year-old woman with a 29-cm occlusion at primary intervention.

‡ Complete reocclusion in a 65-year-old man with a 6-cm occlusion at primary intervention.

§ Segmental reocclusion in a 95-year-old man with a 30-cm occlusion at primary intervention.

subsequent SFA occlusion (complication category C). This complication was managed with a crossover stenting maneuver and had no further sequelae. In the other case, which involved an antegrade access, distal embolization in a single runoff tibial artery was managed successfully by catheter-based aspiration (complication category C). Neither vessel perforation nor laceration due to the needle catheter system occurred.

Follow-up and TLR

Walking capacity was re-established in 4 patients treated for Rutherford category 2-3 claudication (Table 2). Clinical improvement was sustained up to a mean follow-up of 6 months, and there were no TLRs up to this point. One patient had a binary restenosis >50% on ultrasound examination at 6 months without recurrent claudication. Another patient had an asymptomatic segmental femoral reocclusion at 12 months, but no TLR was necessary.

In the 16 limbs with Rutherford category 4-5 ischemia, the only major amputation was the one involving the patient who had a failed revascularization. Two (10%) TLRs were necessary because of delayed wound healing. One patient had a patent femoral artery at the 1-month follow-up (ABI 0.83), but the ABI was reduced to 0.46 at 3 months, with evidence of

significant binary restenosis (>50%). In the other patient, who had medial calcinosis and prior traumatic forefoot amputation, rest pain developed at 6 months owing to complete reocclusion. Although wound healing was not fully achieved at the 6- or 12-month follow-up in both cases, no minor or major amputations were necessary, and the rest pain remained resolved.

DISCUSSION

At the beginning of the endovascular era, the ability to treat CTOs was initially limited primarily by failure to cross the occlusion. With the development of stents to treat failed angioplasty, the most common cause for acute procedural failure in the treatment of CTOs has become the inability to engage the true lumen with the guidewire and/or support catheter after recanalization. To overcome this technical challenge, different re-entry catheters were developed to allow passage of a guidewire into the true lumen distal to the occlusion.^{1,6} We and other groups previously reported the safe and successful application of an IVUS-guided catheter system (Pioneer) for steering the puncture needle to create a re-entry into the true lumen.^{1,6} This system requires a 7-F sheath, is expensive owing to the ultrasound console, and demands additional specific skills, which could limit the widespread use of the device. In

comparison, the Outback LTD catheter system is compatible with a 6-F sheath and uses fluoroscopic navigation that is readily available in any catheterization laboratory or interventional suite. Moreover, because no ultrasound is used, the procedure is less expensive.

While the success rate of subintimal recanalization with standard technique is reported to be up to 85%,^{7–9} revascularization success can be improved to almost 100% by using re-entry devices. However, heavily calcified lesions limited the re-entry success rate to as low as 50% in early reports using the first-generation Outback catheter.⁴ Therefore, the system was redesigned to deploy the needle via a lateral port from the integral hypotube that previously ended in a curved retractable needle.^{1,3,4} Using the redesigned system, we were able to achieve a 95% revascularization rate with the Outback LTD catheter in 20 cases of chronic SFA occlusion. The uncontrolled needle deployment and ineffective penetration of the intima initially reported by Wiesinger et al.⁴ did not occur with the new system in our series.

It usually took several attempts to enter and track the 0.014-wire into the true lumen. Kinking of the 0.014-inch wire should be avoided because it might make it impossible to keep the guidewire within the true lumen while withdrawing the catheter system, especially in cases using crossover access. This problem was the cause for our only failure early in our learning curve. This obviously represents a limitation of the Outback catheter involving crossover maneuvers in patients with tight angulation of the aortic bifurcation.

Comparing fluoroscopy guidance to IVUS navigation, the presence of calcium can limit IVUS imaging, but on the other hand, its presence is an important vessel characteristic for steering the Outback LTD catheter. Although calcium might be a limitation to needle deployment through the intima, all of the cases in our series had severe vessel calcification but were successfully treated. Calcifications may impose an obstacle to catheter advancement through the subintimal space, but this could be resolved with balloon predilation using low-profile catheters. Calcifications might even improve the accuracy of achieving true lumen re-entry at the point desired, which is an advantage that was not

fully recognized before our experience with this new re-entry device. For example, in an SFA occlusion, precise positioning of the re-entry in a reconstituted above-knee popliteal artery may preserve the option of an above-knee femoropopliteal bypass in the event of long-term failure of angioplasty or stenting. Furthermore, the availability of true lumen re-entry devices will broaden the applicability of endovascular recanalization techniques to poor-surgical-risk patients with more severe disease, i.e., elderly patients with critical limb ischemia. Although the application of this needle catheter has been shown to be safe, the potential for perforation and severe bleeding from the puncture side has to be taken into account, and appropriate covered stents should be available when using a needle re-entry system.

Compared to previous reports, the re-entry success rate in our study is improved with the re-engineered system.^{1,3,4} Hausegger et al.³ used the first-generation model of the Outback system in 10 patients with intermittent claudication as a bailout procedure to cross iliofemoral lesions; they reported a success rate of 80%. Using the same model, Wiesinger et al.⁴ reported a success rate of only 50%. The low success rate was attributed to insufficient stiffness and sharpness of the system for penetrating, crossing, and puncturing. In addition, Jacobs et al.¹ reported a failure of 26% with conventional guidewires and guiding catheters in a series of 87 iliofemoral CTOs. In 3 cases, they used the Outback catheter system with 100% success; the other 21 cases were treated with the Pioneer catheter. Compared to the original Outback catheter, the new Outback LTD catheter can be used safely even with a stiffer needle that potentially increases the success rate. In our series, there were no complications related to the new needle system.

As regards TLR, our series demonstrated favorable short-term follow-up, with a 10% TLR rate compared to other studies reporting TLR rates between 30% to 75%.^{7,9} There were 2 significant but asymptomatic restenoses that will, over time, decrease the patency rate and increase the need for vascular follow-up and reintervention depending on the clinical stage. However, although application of the re-entry catheter increases the revascularization suc-

cess rate, recurrent stenosis or occlusion remains a limitation, especially in de novo long occluded segments. Therefore, the evaluation of re-entry catheters must be based on clinical stages and lesion characteristics, as well as a relationship to patency prognosis. In critically ischemic limbs, the higher costs associated with re-entry catheters seem justified, whereas in claudicants, the overall and long-term clinical benefits may not necessarily outweigh additional costs.

Conclusion

The fluoroscopically-navigated Outback LTD needle re-entry system is safe, easy to use, and very effective. It represents the device of first choice as a bailout endovascular option for femoral CTOs in patients with either claudication or critical limb ischemia. Short- and midterm sustained clinical improvement appears favorable.

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